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Acme United Corporation

510(K) SUMMARY

Submitter's Name: Acme United Corporation
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Date of Submission:

"This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990 and 21 CFR 807.92."

The assigned 510(K) number is:

Proprietary Name of Device: Lyofoam® Extra "C" Odor Absorbing
Common/Usual Name: Wound Dressing. Extra absorbent,
non-adherent, odor absorbing, wound
dressing.
Classification Name: Dressing, Class I
Product Claiming
Equivalence To: Lyofoam® "C" Odor Absorbing Wound
Dressing and Lyofoam® Extra
Absorbent, Non-Adherent Polyurethane
Foam Dressing.
Description of Device: Lyofoam® Extra "C" Extra Absorbent,
Non-Adherent Polyurethane Foam
Dressing with activated carbon for
odor absorption.



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Intended Use, Comparison To
Predicate Device:

The Lyofoam® Extra "C" Odor Absorbing Wound Dressing is a combination of the Lyofoam® Extra product and the Lyofoam® "C" Odor Absorbing Wound Dressing Product. The main difference between them is that Lyofoam® Extra is used in place of the regular Lyofoam® for the wound dressing segment of this product. Both have the same activated carbon layer for odor absorption.

The inner absorbent layer of Lyofoam® Extra "C" Odor Absorbing Wound Dressing holds more excess wound fluid than Lyofoam® "C". This would allow the Lyofoam® Extra "C" to be left on the wound without changing for a longer period of time. The Lyofoam® Extra "C" Odor Absorbing dressing is intended for the treatment of moderately to heavily exuding wounds, while Lyofoam® "C" would be used to treat lightly to moderately exuding wounds. Performance data for the Lyofoam® Extra dressing segment of this product can be found in the Lyofoam® Extra 510(K) file K952565.



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Safety:

Safety test data can be found in both the Lyofoam® Extra 510(K) file K952565 and Lyofoam® "C" Odor Absorbing Wound Dressing 510(K) file; K864084. All safety data is summarized in those files and indicates product is safe for use.

Sterility and Packaging:

Lyofoam® Extra "C" Odor Absorbing Wound Dressing is packaged in a paper/foil peep pouch and is sterilized using gamma radiation and has a SAL 10^{-6} .